Chapter 8: Regulations and Associated Publix Policies

Overview

Introduction

This chapter details various legal guidelines and procedures by which Publix Pharmacy associates must abide.

In this chapter

This chapter contains the following topics.

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Overview, Continued

In this chapter, cont'd

Code of Ethics for Pharmacy Associates

Introduction

Publix supports the *American Pharmacists Association's Code of Ethics* and expects our pharmacists to abide by the principles stated in it. This *Code of Ethics*, prepared and supported by pharmacists, states the principles that form the moral obligations that guide pharmacists in their relationships with patients, health professionals, and society.

Additionally, Publix has adopted its own Code of Ethics. In order to successfully carry out Publix's mission, all pharmacy associates must adhere to Publix's Code of Ethics.

APhA *Code of Ethics*

The American Pharmacists Association (APhA) declares the following *Code of Ethics*.

- *A pharmacist respects the covenantal relationship between the patient and pharmacist*. Considering the patient-pharmacist relationship as a covenant means that a pharmacist has moral obligations in response to the gift of trust received from society. In return for this gift, a pharmacist promises to help individuals achieve optimum benefit from their medications, to be committed to their welfare, and to maintain their trust.
- *A pharmacist promotes the good of every patient in a caring, compassionate, and confidential manner.* A pharmacist places concern for the well being of the patient at the center of professional practice. In doing so, a pharmacist considers needs stated by the patient as well as those defined by health science. A pharmacist is dedicated to protecting the dignity of the patient. With a caring attitude and a compassionate spirit, a pharmacist focuses on serving the patient in a private and confidential manner.
- *A pharmacist respects the autonomy and dignity of each patient.* A pharmacist promotes the right of self-determination and recognizes individual self-worth by encouraging patients to participate in decisions about their health. A pharmacist communicates with patients in terms that are understandable. In all cases, a pharmacist respects personal and cultural differences among patients.
- *A pharmacist acts with honesty and integrity in professional relationships.* A pharmacist has a duty to tell the truth and to act with conviction of conscience. A pharmacist avoids discriminatory practices, behavior or work conditions that impair professional judgment, and actions that compromise dedication to the best interests of patients.
- *A pharmacist maintains professional competence.* A pharmacist has a duty to maintain knowledge and abilities as new medications, devices, and technologies become available and as health information advances.

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Code of Ethics for Pharmacy Associates, Continued

APhA *Code of Ethics*, continued

- *A pharmacist respects the values and abilities of colleagues and other health professionals.* When appropriate, a pharmacist asks for the consultation of colleagues or other health professionals or refers the patient. A pharmacist acknowledges that colleagues and other health professionals may differ in the beliefs and values they apply to the care of the patient.
- *A pharmacist serves individual, community, and societal needs.* The primary obligation of a pharmacist is to individual patients. However, the obligations of a pharmacist may at times extend beyond the individual to the community and society. In these situations, the pharmacist recognizes the responsibilities that accompany these obligations and acts accordingly.
- *A pharmacist seeks justice in the distribution of health resources.* When health resources are allocated, the pharmacist is fair and equitable, balancing the needs of patients and society.

Publix *Code of Ethics*

At Publix, we are committed to conducting our business with the highest standards of integrity. Our associates, customers, stockholders, suppliers, and communities expect us to uphold high standards of ethical behavior. The Publix *Code of Ethics* published in the *Managers' Reference Library* (MRL), is intended to give associates a guide to the ethical standards we must maintain. If you have any questions, please contact your manager.

Confidentiality

Introduction

All Pharmacy associates must have an understanding of the need for confidentiality regarding our patients' medical records.

Customer prescriptions contain private, personal information. You must respect the privacy of our customers to maintain their trust and to comply with legal and ethical standards.

Policy

All information pertaining to patients must be maintained in the strictest confidence. Never disclose any patient information to anyone outside the Pharmacy unless specifically authorized by the Pharmacist in charge. Any disclosure, even to other associates within the Pharmacy, will be strictly on a need-to-know basis.

Any Publix associate who has access to a patient's medical records is required to have a signed *Confidentiality Agreement* and a *Information Resources Policy* filed in his or her Personnel File Folder.

Protected health information (PHI)

All Pharmacy associates must take every reasonable precaution to safeguard a patient's protected health information (PHI), including oral information, from any intentional or unintentional uses or disclosures, when providing treatment, collecting payment for treatment, and conducting certain health care operations. See *Chapter 7* for more information on PHI.

Handling of records

Consider these confidentiality rules.

- Never copy or remove records of patient information from the premises except as specifically authorized by the Pharmacist in charge.
- Health Insurance Portability and Accountability Act of 1996 (HIPAA) provides rules governing the use and disclosure of protected health information (PHI). See *Chapter 7* for more details on *HIPAA* and *PHI*.
- Records may be released pursuant to a valid subpoena. (See the *Handling Requests to Access Records (PHI)* section in *Chapter 7* for more information.) However, in no event may records which would disclose patient information regarding AIDS, HIV, or sexually transmitted diseases be released pursuant to a subpoena.
- Records may be released pursuant to a valid authorization. (See the *Handling Requests to Access Records (PHI)* section in *Chapter 7* for more information.)
- State laws may contain restrictions on uses and disclosures of PHI.

Conscientious Objection

Introduction

Some Pharmacists may have a conscientious objection to filling certain prescriptions (for example, abortifacient and contraceptive drugs). Publix policy addresses this circumstance.

Policy

Every Pharmacist has the right to refuse to dispense a prescription based on religious, moral, or ethical grounds. However, as part of our policy, Publix customers must be accommodated and be able to receive any prescription product that's legally prescribed by a physician. Publix will have on staff in each Pharmacy a dispensing Pharmacist who's able to serve all of our customers.

Notification

Any Pharmacist who is a conscientious objector must notify the Pharmacy Supervisor of his or her position. This notification must be done *before* refusing to fill any customer's prescription on these grounds.

Publix's Policy Regarding Substance Abuse

Introduction

Publix is committed to providing and maintaining a working environment free of substance abuse. Substance abuse often leads to performance deficiencies, increased operating costs, and injuries to associates and their coworkers.

Publix is primarily concerned with substances that may affect an associate's mental or physical ability to function normally at work. It's important that associates understand Publix has designed preventative, as well as disciplinary, measures to maintain working environments free of substance abuse.

Prohibited conduct under Publix's Substance Abuse Policy

The following is prohibited under Publix's Substance Abuse Policy

- *selling* or distributing any drug, including a prescription drug, whether on or off duty, unless the associate is legally authorized to sell or distribute the substance in question under the circumstances
- *possessing* any illegal drug on Publix premises at any time
- *using* any illegal drug at any time (This includes out-of-date or expired prescription drugs, prescription drugs prescribed for someone else, or current prescription drugs not used according to the prescription. Medications over 24 months old are considered out-of-date when prescribed on an as needed basis.) and
- *drinking* alcohol while on the job or reporting to work under the influence of alcohol.

Drug Testing

Applicants that are offered a position at Publix are drug tested before they are hired. Associates working for Publix are subject to random drug testing. The method and location of testing are chosen by Publix.

Refusing to submit to testing is failing to

- appear for a test within the required timeframe
- remain at the collection site until the testing process is complete
- provide a specimen or cooperate with any part of the testing process and
- provide a sufficient amount of urine without a valid medical explanation.

Applicants who refuse to submit to testing will be ineligible for employment for one year. Associates who refuse to submit to testing should be terminated.

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Publix's Policy Regarding Substance Abuse, Continued

Prescription Documentation for Associates Working in Publix Pharmacy

Associates working in Publix pharmacies must follow these requirements regarding their own personal prescriptions.

- If you are taking a prescription medication, you MUST have a valid prescription for this product. The prescription must be for you and must be filled within State/Federal prescription date guidelines.
- If you are taking a PRN (non-routine) medication, make sure your prescription is NO MORE THAN 2 years old. Medications over 24 months old are considered out-of-date when prescribed on an as needed basis.
- If you are selected for a random drug screen and are taking a prescription medication, be prepared to produce a prescription bottle and/or a prescription that was written or has been filled within the last 24 months.
- Publix has a VERY STRICT no tolerance policy. If you are tested, found to be positive for a product, and do not have the above noted supporting documentation, you WILL NOT be allowed to work in the Pharmacy for a period of 3 years.

Prescription drugs and safety

An associate taking prescribed drugs must ensure that the use of the drugs doesn't affect his or her performance or his or her ability to perform assignments safely. If an associate feels prescribed drugs may affect his or her performance, safety, or the safety of others, then the associate should share these concerns with his or her manager, Retail Associate Relations Specialist, or a representative of the Employee Assistance Program (EAP) department so that accommodations may be considered. In some circumstances, it may be appropriate to request a note from the associate's physician stating that the associate is capable of safely performing job duties.

Additional Information or Questions

For more information on Publix's Substance Abuse Policy, see the *Managers' Reference Library* (*MRL*) or contact your Pharmacy Supervisor with any questions.

Pharmacist Liability Insurance

Introduction

Like many retailers and pharmacies, Publix self insures most of the financial risk associated with pharmacy quality related events and malpractice claims. In those situations in which Publix either resolves a claim or lawsuit or is found by a court or jury to be liable, Publix is fully responsible for any legal fees, settlement or verdict within its self–insured retention.

Defending and Indemnifying Publix Pharmacists

Publix will provide a legal defense and include the Pharmacist in any settlement or resolution of a claim involving allegations of a quality related event or malpractice as long as, in Publix' sole determination, the Pharmacist acted within the course and scope of his or her job duties, and did not engage in any intentional or negligent acts (or failures to act).

Publix will provide a legal defense and include the Pharmacist in any settlement or resolution of any other type of claim other than quality related events or malpractice as long as, in Publix' sole determination, the Pharmacist acted within the course and scope of his or her job duties.

These decisions are made by Publix on a case-by-case basis.

Pharmacists' Responsibility

If a Pharmacist's actions involving either a quality related event or malpractice results in a verdict against Publix or the settlement of a claim or lawsuit, Publix may seek contribution or indemnification from the individual Pharmacist or from any insurance policy maintained by an individual Pharmacist for any loss Publix suffers. Publix's decision to seek contribution or indemnification from any individual Pharmacist or his or her insurance company will be made on a case-by-case basis considering all the facts known to Publix at the time Publix might make such a request.

Hartford Excess Druggist Liability Insurance Policy

In addition to self insurance, Publix maintains an Excess Druggist Liability Insurance policy issued by the Hartford. Subject to the terms of the Policy, the Hartford Excess Druggist Liability Policy provides coverage to any associate acting within the scope of his or her employment while performing duties related to pharmacists' professional services. However such coverage only applies to the extent costs, fees, judgments or settlements paid by Publix exceed the self-insured retention.

Pharmacists' Liability Insurance

Publix does not purchase insurance which specifically covers individual Pharmacists in all situations. Many Pharmacists choose to carry their own personal, professional malpractice insurance.

Pharmacy Laws

Introduction

Each state has documented laws and rules pertaining to the practice of pharmacy. In addition to state laws, all pharmacists must meet federal requirements to practice pharmacy.

State laws

Each state in which Publix operates a Pharmacy has a governing Board of Pharmacy. The Board of Pharmacy has the authority to, but is not limited to

- adopt rules and implement the rules pursuant to any state or federal statute, rule, or regulation
- examine each applicant who has applied to the board for licensure and has completed certain requirements
- process the renewal of licenses
- apply and set fees and expenditures to applicants
- set and monitor professional pharmaceutical continuing education (CE) requirements
- adopt a Standard of Practice
- carry out any disciplinary action set forth by the state rules or regulations and
- inspect any pharmacy (in a lawful manner).

Required access to state manuals

Each Publix Pharmacy is required by law to have access to the current pharmacy laws and rules that apply to its respective state. These laws and rules are located at Pharmacy Online. Make sure the current laws, in addition to this *Pharmacy Reference & Procedures Guide*, are easily accessible to all Publix Pharmacy associates to guide them in their practice.

Federal laws

In addition to state laws, all pharmacies are required to comply with federal laws pertaining to the practice of pharmacy that include, but are not limited to

- the Federal Controlled Substance Act
- the Federal Food, Drug, and Cosmetic Act
- the Comprehensive Drug Abuse Prevention and Control Act
- the Omnibus Budget Reconciliation Act of 1990 (OBRA '90) and
- the Health Insurance Portability and Accountability Act of 1996 (HIPAA).

Questions

If you have any questions about a pharmacy law or rule or how to access these laws, contact your Pharmacy Supervisor or divisional Pharmacy Operations Manager.

Methamphetamine Abuse Regulations

Introduction

The U.S. Congress passed the USA PATRIOT Improvement and Reauthorization Act of 2005, which includes a number of provisions relating to the sales of products containing pseudoephedrine, ephedrine, and phenylpropanolamine. The President signed this legislation on March 9, 2006. Included in the Act are provisions concerning Methamphetamine, which impose certain restrictions and requirements with respect to the sale of psuedoephedrine, ephedrine, and phenylpropanolamine products.

Summary of Federal Law

This chart contains key elements of the Federal Law regarding methamphetamine abuse regulations.

Subject	Description
Affected Products	All pseudoephedrine (PSE), ephedrine (EPH), and phenylpropanolamine (PPA) products are classified under the Federal Controlled Substances Act (CSA) as "scheduled listed chemical products."
Product Restrictions	Non-liquid dosage forms (including gel caps) of the affected products must be in blister packaging or unit dose packaging, with no more than 2 dosage units per blister.
Sales Limits	Individual customer sales are limited to 3.6 gm/ day of PSE, EPH, or PPA base product. This daily sales limit is to be based on a calendar day.
Purchase Limits	Individual customer purchases are limited to 9 gm/ 30 day period of PSE, EPH, or PPA base product. This monthly purchase limit will be based on a calendar month. (The reference to a "purchase" limit means the responsibility to meet this limitation is on the customer. However, a retailer may not act recklessly in selling the products.)
Product Placement	Affected products must be stored behind a counter or in a locked cabinet.
ID Requirements	Consumers must show a federal or state issued photo ID, or an alternative form of ID acceptable by INS/DHS regulations, except for sales of PSE that are 60 mg or less, for which no ID requirement exists.

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Methamphetamine Abuse Regulations, Continued

Summary of Federal Law , continued

Subject	Description
Log and Other Recordkeeping Requirements	• Purchasers must sign a written or electronic log into which they have entered their name and address, and date and time of sale; and into which the seller has entered name and quantity of the product, <u>except for sales of PSE that are 60 mg or less, for which there is no log requirement</u>. • Log must be maintained for two years after date of last entry. • Privacy protections exist for information in the logs • Log must show a misrepresentation warning to purchaser; warning must include notice of maximum fine and term of imprisonment.
Training Requirements	• Individuals who deal directly with purchasers must undergo training provided by their employer. Employers must certify with Attorney General that all employees have been trained.

State Law Restrictions

Retailers must comply with state and local laws, as well. If there is a conflict between a provision of federal law and a state or local law, then Publix must comply with the most stringent provision.

Listed below are individual state restrictions that you should be aware of for the state in which you practice.

State	Law
Florida	• Product must be maintained and sold from behind the counter. • See FL Code Ch. 893-1495.
South Carolina	• Product must be maintained and sold from behind the counter. • See SC Code § 44-53-398.

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Methamphetamine Abuse Regulations, Continued

State Law Restrictions, cont'd

State	Law

Alabama	• Individual customer purchases are limited to 7.5 gm/ 30 day of PSE, EPH, or PPA base product.
	• If a purchaser resides in another state and that state requires a prescription, then the purchase requires a prescription in AL.
	• Product must be maintained and sold from behind the counter.
	• ID restrictions are a little more stringent only allowing:
	  • valid, unsuspended driver's license or non driver identification card issued by this state
	  • valid, unsuspended driver's license or non driver identification card issued by another state
	  • US passport
	  • Foreign Passport
	  • US Uniformed Services Privilege and Identification Card
	• See AL Code §20-2-190.

Georgia	• Whenever a pharmacy in Georgia receives, purchases, or otherwise gains access to products containing PSE from any wholesale distributor, such pharmacy must maintain copies of all invoices, receipts, and other records regarding PSE products for a minimum of 3 years from the date of receipt, purchase or access (GA Code 16-13-30.4). • Pharmacies must maintain an electronic or paper logbook and it must be maintained for 2-years. • Product must be maintained behind the counter and only sold by a registered pharmacist or registered intern under the supervision of a pharmacist. • See GA ruling 480-19-.03 through .05.
Tennessee	• Products containing EPH, PSE or PPA may only be dispensed in a licensed pharmacy and can be maintained, by law, behind the counter or in a locked cabinet within 25 feet and in view of the pharmacy. Note: At Publix, we choose to keep this product behind the counter. • Tennessee Law restricts individual sales to 9gm/30 day period. This means there is more responsibility on the pharmacy staff to track the sales. • See TN Code § 39-17-431.

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Methamphetamine Abuse Regulations, Continued

Plan-o-gram for products

At Publix, PSE products must be maintained behind the pharmacy counter. Work with your Pharmacy Supervisor to determine the best location for displaying these items.

You are responsible for maintaining inventory of all items listed on the *OTC Core Item List* which includes PSE products. This list can be found on the pharmacy portal page in the Procurement section, under *OTC Core Items*. These products can be ordered through our wholesaler.

You are also responsible for maintaining and displaying PSE aisle cards for our customers when they are looking for product in the OTC aisle or display areas outside of your pharmacy.

Selling PSE in GA

When processing the sale for PSE products in the state of Georgia, all drug products containing pseudoephedrine are classified as exempt over-the-counter (OTC) schedule V controlled substances. According to these regulations,

- each pharmacy is required to maintain a log of all PSE sales for two (2) years from the date of last entry
- a registered pharmacist or pharmacy intern under the supervision of a pharmacist must approve all sales transactions by signing the logbook in the appropriate column which documents verification of
  - patient identification
  - valid medical reason, and
  - logbook entry is complete.

Note: The Logbook is orderable from Printing Services by accessing the Pharmacy Supply Order Form on Publix Connection (RC1180 COMBAT METH LOG FOR GA ONLY).

The products have been flagged in our POS system. When a customer attempts to buy more than **ONE** item in a single transaction, the register will lock up and not allow the second item to scan. If more than one product is within the sales and purchase limits the second item must be rung up as a separate transaction.

Note: Do not use the "generic" Pharmacy Bar Code to ring these items up – the quantity limits set in the system will not apply properly.

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Methamphetamine Abuse Regulations, Continued

Selling PSE in AL, FL, SC, and TN

When processing the sale of PSE products in the states of Alabama, Florida, South Carolina, and Tennessee, you must follow the requirements below.

- The sale must be entered into the National Precursor Log Exchange (NPLEx) before ringing up the sale and providing product to the customer. Use of the NPLEx system is required by state law. The NPLEx system will verify whether or not the purchase meets daily and monthly limits based on state and Federal laws.
  - The NPLEx website link is on the Home page of your pharmacy system.
  - Procedures for access and use of this website are posted on the pharmacy page of Publix Connection - *Compliance > PSE.*
- Each pharmacy is required to maintain a log of all PSE sales using the Combat Meth Log (RC0270).
  - This Log contains the purchase date, NPLEx transaction number, seller's initials, and purchasers signature. This is required by law.
  - In each state the Log must be maintained in your pharmacy for two (2) years from date of last entry.

  Note: The Log is orderable from Printing Services by accessing the Pharmacy Supply Order Form on Publix Connection (RC0270 COMBAT METH LOG AL, FL SC & TN).
- The products have been flagged in our POS system. When a customer attempts to buy more than **ONE** item in a single transaction, the register will lock up and not allow the second item to scan. If more than one product is within the sales and purchase limits the second item must be rung up as a separate transaction.

Note: Do not use the "generic" Pharmacy Bar Code to ring these items up – the quantity limits set in the system will not apply properly.

Equivalency Charts

Equivalency charts for the daily sales limits and monthly purchase limits for PSE PSE, EPH or PPA containing products are located on the pharmacy page of Publix Connection - *Compliance > PSE.*

iPledge Program

Introduction

Because of Isotretinoin's potential to cause birth defects, the FDA set up the iPledge program. It is a special distribution program that allows the marketing and distribution of isotretinoin.

Overview of iPledge Program requirements

Prescribers, patients, pharmacies, and manufacturers/wholesalers must follow specific requirements under the iPledge program.

Isotretinoin must only be

- prescribed by physicians who are registered and activated with the iPledge program
- dispensed from registered and activated pharmacies by pharmacists who have received authorization from iPledge
- received by registered patients actively enrolled in the program and
- delivered to pharmacies by registered manufacturers/wholesalers.

Responsible Site Pharmacist

Each pharmacy must designate a pharmacist as the Responsible Site Pharmacist. This pharmacist

- registers with iPledge as the Responsible Site Pharmacist
- activates the pharmacy registration, initially and annually, and
- trains all on-site pharmacists to fill isotretinoin.

The Responsible Site Pharmacist can be changed at any time by accessing iPledge via telephone or internet.

Overview of use of Isotretinoin

Isotretinoin is used to treat severe recalcitrant nodular acne, and is limited to a maximum 30-day supply with no refills. It is teratogenic and must NOT be used by pregnant woman, and should not be shared. Women should not become pregnant within one month of discontinuing isotretinoin therapy.

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iPledge Program, Continued

Dispensing procedures

To dispense isotretinoin, the dispensing pharmacist must follow these steps.

Step	Action
1	Access iPledge at 1-866-495-0654 or www.ipledgeprogram.com. To access iPledge, the dispensing pharmacist will need the • pharmacy NCPDP number, and • pharmacy password (given upon activation of the pharmacy account). Note: The website is located on Publix Connection under the Store tab - Store → Pharmacy → Drug Information → Isotretinoin - iPLEDGE.)
2	Follow the iPledge prompts for filling a prescription. Note: The dispensing pharmacist will need the patient's iPledge ID card which contains the patient's ID number and date of birth.
3	Did you receive authorization to fill the prescription? **If...** / **Then...** Yes → • follow the instructions for entering the patient's prescription information (e.g., NDC, days supply), and • go to the next step. No → inform the patient of the next steps as provided by the iPledge system. *Do not fill the prescription.*
4	Receive a Risk Management Authorization (RMA) number and record it on the hard copy prescription.
5	Receive a "Do Not Dispense to Patient After" date and records it on the prescription bag sticker provided by iPledge. Note: The prescription window for female patients of childbearing potential is 7-days from the office visit date. However, the prescription window for female patients not of childbearing potential and males has been extended from 7 days to 30 days.

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iPledge Program, Continued

Dispensing procedures, cont'd

Step	Action
6	Complete and fill the prescription. • Enter the prescription information on the *Prescription Filling* screen. • Enter the RMA number provided by iPledge in the *Rx Message* field (located to the right of the *Rx NUM* field at the top of the screen). • **Tab** down to the *TPFlag* field → Hit **Enter** → Select **1** (Prior Authorization #) → **Tab** once→ Enter **999999999** in the *PA#* field → Hit the **End** button. • Continue processing the prescription. Note: The maximum days supply is 30. Refills are not allowed. Each month the patient would be required to satisfy program requirements for a new prescription.
7	Dispense the prescription to the patient if the patient picks up the prescription by the "Do Not Dispense to Patient After" date. Note: *The pharmacist **must not dispense** the prescription after this date.*

Note: The drug comes in a blister pack of ten capsules which can not be broken.

Returning to stock

If product is returned to stock because the patient didn't pick it up in time, iPledge must be notified so they can reverse the authorization. Notify iPledge via the telephone or website and follow the prompts to reverse a prescription.

Ordering supplies

Additional supplies, including *Do Not Dispense After* stickers and program brochures, can be ordered by accessing the **Order Materials** link on the iPLEDGE website.

Fraud and Abuse - Overview

Introduction

Publix Pharmacy is committed to its role in preventing and eliminating healthcare fraud and abuse. Our failure to observe healthcare fraud and abuse laws can result in serious consequences for Publix and Publix associates, including termination of employment, civil penalties, exclusion from participation in federal healthcare programs, criminal prosecution, and damage to Publix's reputation.

Definition of fraud and abuse

The Centers for Medicare and Medicaid Services (CMS) is the federal agency responsible for overseeing the financial integrity of the Medicare program and the states' Medicaid fraud and abuse control activities. CMS defines fraud and abuse as follows:

Fraud. The intentional deception or misrepresentation that an individual knows to be false (or does not believe to be true) and makes, knowing that the deception could result in an unauthorized benefit to himself or another person.

Abuse. Incidents or practices of healthcare providers that are inconsistent with sound medical practice and that may result in unnecessary costs, improper payments, or the payment for services that either fail to meet professionally recognized standards of care or that are medically unnecessary.

Examples of suspected healthcare fraud and abuse associated with billing activities

Fraud and abuse conduct occurs when a healthcare provider intentionally defrauds the government through the submission of claims for payment. Fraud and abuse conduct does not include inadvertent or innocent billing mistakes. The following billing activities of pharmacies may be suspected instances of fraud and abuse:

- Billing for drugs or supplies that were not dispensed.
- Billing for brand name drugs when generic drugs were dispensed.
- Billing for drugs as "covered" under a benefit plan when "non-covered" drugs were dispensed.
- Billing for drug samples.
- Failing to reverse claims for unused, returned prescriptions.
- Improperly billing multiple payors for the same dispensed drugs or supplies.
- Routinely waiving beneficiary co-payments.
- Inflating the bills for drugs or supplies.
- Using improper procedure or product coding (upcoding or unbundling).
- Billing healthcare programs for ineligible beneficiaries.
- Billing for prescriptions that are filled but not dispensed, i.e., never picked up by the patient.

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Fraud and Abuse - Overview, Continued

Other examples of suspected healthcare fraud and abuse

The following activities, when performed in connection with the submission of pharmacy claims, may be suspected instances of healthcare fraud and abuse:

Prescription Drug Shorting. Providing less than the prescribed quantity and intentionally not informing the patient or making arrangements to provide the balance, but billing for the fully-prescribed amount.

Bait and Switch Pricing. Leading a beneficiary to believe that a drug will cost one price but, at the point of sale, charging the beneficiary a higher amount.

Prescription Forging or Altering. Altering existing prescriptions without the prescriber's permission in order to increase the quantity or number of refills.

Dispensing Expired or Adulterated Prescription Drugs. Dispensing drugs that are expired or that have not been stored or handled in accordance with manufacturer or U.S. Food and Drug Administration requirements.

Prescription Refill Errors. Providing the incorrect number of refills authorized by the prescribing provider.

Engaging in Illegal Remuneration Schemes. Offering or paying, or soliciting or receiving, unlawful remuneration to induce or reward the pharmacy to switch patients to different drugs, influence prescribers to prescribe different drugs or steer patients to certain health plans.

TrOOP Manipulation. Manipulating a beneficiary's true out of pocket costs ("TrOOP") to either push beneficiaries through a plan coverage gap before they are eligible, or manipulating TrOOP to keep a beneficiary in a plan coverage gap.

Failure to Offer Negotiated Prices. Failing to offer a Medicare Part D beneficiary the negotiated price for a Part D covered drug.

Failure to Adhere to CMS' Marketing Guidelines. Failing to follow CMS' instructions for pharmacies on the marketing 'do's and don'ts' of participating in and assisting beneficiaries with Medicare Part D plans.

Fraud and Abuse – Applicable Laws

Introduction

The federal government and certain states have enacted laws pertaining to the submission of false or fraudulent claims for payment by federal and state agencies or private payors. A violation of these false claims laws may result in criminal, civil, and administrative penalties. Government agencies have broad authority under these laws to investigate and prosecute potentially fraudulent conduct.

About the Federal Civil False Claims Act

The federal Civil False Claims Act (FCA) forbids knowing and willful false statements or representations made in connection with a claim for payment submitted to the U.S. Government (or its agents and contractors) including federal healthcare programs, such as Medicare or Medicaid. The FCA also forbids the knowing concealment or improper avoidance of an obligation to pay the U.S. Government when there is an established duty to do so. The FCA extends to individuals who have actual knowledge of the falsity of the information, as well as individuals who act in deliberate ignorance or in reckless disregard of the truth or falsity of the information.

Penalties under the FCA include fines from $5,500 to $11,000 per false claim, payment of treble damages, and exclusion from participation in federal healthcare programs.

The FCA contains a whistleblower provision, which allows someone (whistleblower) with actual knowledge of alleged FCA violations to file suit on the federal government's behalf. After the whistleblower files suit, the case is kept confidential while the government conducts an investigation to determine whether it has merit. The government may decide to take over the case, but if it declines to do so, the whistleblower still may pursue the suit. A whistleblower who prevails may qualify for 15 to 30 percent of the amount recovered on the government's behalf, as well as attorneys' fees and costs.

The FCA prohibits employers from retaliating against employees (or against agents and contractors of the employer) who lawfully file or participate in the prosecution of a whistleblower suit. An employee who suffers unlawful retaliation from his or her employer (e.g., discharged, demoted, suspended, threatened, harassed, or in any other manner discriminated against in terms and conditions of employment because of lawful acts done by the employee) may receive certain relief such as back pay, reinstatement or compensation for damages sustained as a result of the improper discrimination.

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Fraud and Abuse – Applicable Laws, Continued

Florida False Claims Act

The Florida False Claims Act (FFCA) authorizes Florida to bring civil actions against persons who cause the state, including Florida Medicaid, to pay claims that are false or fraudulent.

Similar to the FCA, FFCA forbids a person from knowingly presenting a false of fraudulent claim to a Florida agency, including Florida Medicaid. The FFCA extends to individuals who have actual knowledge of the falsity of the information, as well as individuals who act in deliberate ignorance or in reckless disregard of the truth or falsity of the information.

Penalties under the FFCA include fines from $5,500 to $11,000 per false claim, payment of treble damages, and the costs of any civil action brought to recover such penalties or damages.

The FFCA contains a whistleblower provision, which allows someone with actual knowledge of alleged FFCA violations to file suit on the state government's behalf. After the whistleblower files suit, the case is kept confidential while the government conducts an investigation to determine whether it has merit. The government may decide to take over the case, but if it declines to do so, the whistleblower still may pursue the suit.

The FFCA protects employees from retaliation (e.g., being discharged, demoted, suspended, threatened, harassed, or in any other manner discriminated against in the terms and conditions of employment) by their employer when the employee's actions are lawful under the FFCA.

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Fraud and Abuse – Applicable Laws, Continued

Georgia False Claims Act

The Georgia False Medicaid Claims Act (FMCA) authorizes Georgia to bring civil actions against persons who cause Georgia Medicaid to pay claims that are false or fraudulent.

Similar to the FCA, FMCA forbids a person from knowingly presenting a false or fraudulent claim for reimbursement to Georgia Medicaid. The FMCA extends to individuals who have actual knowledge of the falsity of the information, as well as individuals who act in deliberate ignorance or reckless disregard of the truth or falsity of the information.

Sanctions for violating FMCA include civil penalties between $5,500 and $11,000 for each false or fraudulent claim, treble damages and other civil fines.

The FMCA contains a whistleblower provision, which allows someone with actual knowledge of alleged FFCA violations to file civil suit on the state government's behalf. The Georgia Attorney General may intervene in an FMCA whistleblower suit; however, if the Attorney General elects not to intervene then the whistleblower has the right to conduct the civil action.

The FMCA protects employees from retaliation (e.g., being discharged, demoted, suspended, threatened, harassed, or in any other manner discriminated against in the terms and conditions of employment) by their employer when the employee's actions are lawful under the FMCA.

Fraud and Abuse – Prevention and Detection

Introduction

It's important to do our part to prevent and detect healthcare fraud and abuse at Publix.

Publix Non-Retaliation Policy

It is Publix's policy to carefully review every legitimate report of wrongdoing and to not take disciplinary action against an associate for reporting wrongdoing, in good faith, to Publix or to government officials.

Pharmacy Staff Responsibilities

Pharmacy staff at retail locations are expected to prevent and detect fraud and abuse by:

- following key billing procedures included in the *Pharmacy Reference and Procedures Guide* and Pharmacy Online;
- calling our centralized support desk for pharmacy billing assistance (863-688-1188, x54004);
- complying with Publix's Code of Conduct (see your store's *Managers' Reference Library*);
- complying with Publix's Code of Ethics (see your store's *Managers' Reference Library*, as well as page 8-2 in the *Pharmacy R&P Guide*); and
- reporting questionable fraud and abuse conduct occurring at the Pharmacy using the reporting mechanisms described on the next page.

How to Report Questionable Activity

Publix requires each associate to report conduct that a reasonable person would believe to be healthcare fraud and abuse. Each associate may report any such suspected instances of fraud and abuse to his or her Pharmacy Supervisor or to the Publix Corporate Counsel department. An associate may also anonymously report suspected fraud and abuse to the Publix Ethics Hotline (1-866-747-3773).

Tamper-Resistant Prescription Pads

Introduction

Starting April 1, 2008 in order for Medicaid outpatient drugs to be reimbursable by the federal government, all written, non-electronic prescriptions must be executed on tamper-resistant pads.

This requirement was included in section 7002(b) of the U.S. Troop Readiness, Veterans' Care and Katrina Recovery and Iraq Accountability Appropriations Act of 2007. The rule requires that the Medicaid programs have policies and procedures in place to support this requirement. Not doing so could lead to reduced funding for prescriptions from the federal government for the states.

Important

This means that the Medicaid program can recoup monies from us for prescriptions that are not written on tamper-resistant prescription pads.

Characteristics of tamper-resistant prescription pads

CMS outlined three baseline characteristics of tamper-resistant prescription pads. The prescription must be written on paper that:

- prevents unauthorized copying of a completed or blank prescription form, or
- prevents the erasure or modification of information written on the prescription by the prescriber, or
- prevents the use of counterfeit prescription forms.

Effective date

Beginning April 1, 2008, states are requiring the prescription paper to meet one of the three characteristics of tamper-resistant prescription pads.

By October 1, 2008, all three characteristics will need to be met.

Exceptions

As noted earlier, the law applies to written, fee-for-service Medicaid prescriptions. Exceptions to this requirement include the following.

- Prescriptions received electronically (e-prescribing), via telephone or fax.
- Prescriptions for Medicaid eligible recipients enrolled in Managed Care Organizations (AVMED, AmeriGroup, Wellcare, PeachState, etc.)
- Prescriptions provided in nursing facilities or intermediate care facilities for the mentally retarded and the drug is reimbursed as part of the total service and is not reimbursed through the outpatient pharmacy program.
- Refills for which the original prescription was filled before April 1, 2008.

continued on next page

Tamper-Resistant Prescription Pads, Continued

What are Tamper-Resistant Pads?

CMS has not clearly defined tamper-resistant pads in the final rules.

There are various tamper-resistant methods that use technology to create prescription pads that will show evidence of tampering. Below are some examples that are being used or may be used in the future.

- The following technology is used to detect unauthorized copying.
  - High-security watermark imbedded on the reverse side of the blank.
  - Thermochromic ink technology where a copied prescription blank shows the word 'Copy', 'Illegal' or 'Void.'
- Tamper-resistant background ink is used to detect erasures or attempts to modify written information on the prescription.
- Use of duplicate or triplicate blanks is used to prevent the use of counterfeit prescription forms.

State Rules

Each state website has documentation about the application of this regulation to prescriptions written in each state. Find this information on the Pharmacy intranet page by going to *Store → Pharmacy →Managed Care → Medicaid,* then click on the state-specific website.

Below is a chart summarizing key state law requirements.

State	Rules
Alabama	Prescriber can choose type of tamper-resistance pads as long as it complies with at least one of the three CMS characteristics.
Florida	A tamper-resistant prescription pad requirement is already in place for Medicaid prescriptions to meet all three CMS characteristics and should be used by prescribers.
Georgia	Prescriber can choose type of tamper-resistance pads as long as it complies with at least one of the three CMS characteristics.
South Carolina	Prescriber can choose type of tamper-resistance pads as long as it complies with at least one of the three CMS characteristics.
Tennessee	Presriber can choose type of tamper-resistance pads as long as it complies with at least one of the three CMS characteristics. If you are unable to obtain a compliant prescription and as a result are unable to fill the prescription, you **must** provide the TennCare enrollee with a copy of the *Non-Tamper Resistant Notice* as required by the Grier Consent Decree. This explains and informs the enrollee of their right to an appeal. This is a special version of the Grier notice that only applies to Non-Tamper Resistant situations. Note: English and Spanish versions of the document can be downloaded from the TennCare website.

continued on next page

Tamper-Resistant Prescription Pads, Continued

Tips for assessing hard copy prescriptions against the requirements

Prescriptions that are computer-generated do not necessarily meet the tamper-resistant requirement unless they are printed on tamper-resistant paper. If you are not sure, you must confirm with the prescriber.

Prescriptions that are written in ink are not necessarily tamper-resistant, unless they are written on tamper-resistant paper. Ink is not an industry recognized standard for tamper-resistant.

Prescriptions written for individuals that are dually covered with a primary insurance and Medicaid must be written on tamper-resistant paper.

Prescriptions that are written for individuals with retroactive Medicaid coverage must comply with the tamper-resistant rule. Obtaining verbal confirmation from the prescriber and documenting it on the original prescription satisfies this requirement.

Prescriptions for Medicaid eligible individuals that are transferred between pharmacies orally, faxed or electronically are generally considered compliant if the original prescription was compliant.

Handling prescriptions that don't meet the requirements

If a prescription does not meet the tamper-resistant characteristics or you are unsure, contact the prescriber and explain the situation. Request from the prescriber a verbal, faxed, electronic or compliant written prescription.

You can fill the prescription(s) as long as the replacement is received within 72 hours. The 72 hour restriction only applies to the time for getting the compliant prescription, not to the amount of medication you can provide. You may dispense the prescription for the quantities and days supply indicated within the rules of the program.

Audit tip

If you take the prescription over the phone, make sure you document the name of the person you spoke with, the date and time on the prescription. In the case of an audit or inspection, this documentation is critical. In the event that you attempt to obtain a compliant prescription, but are not successful, there is no provision to hold you harmless. ‘

Document Retention and Disposal

Why this is important

Publix Pharmacies must retain certain pharmacy documents for specified time periods to comply with state, federal, and insurance requirements.

Time requirements

Use this table as a reference for document retention time requirements.

Document	Retention Time
Medicare B Enrollment forms	10 years
Medicare Part B *Beneficiary Documentation Receipt Form*	10 years
Medicare Part B *DMEPOS Product Set Up and Deliver Form*	10 years
Prescription hard copies	10 years
Medicaid temporary ID card (FL & GA)	5 years
Prescription Log Book	10 years
Dispensing Record Log (FL, SC, TN, AL)	2 years
Daily Log (GA)	2 years
PPCQIP Quarterly Meeting Agenda and *Summarization of QRE* forms (FL)	2 years
Schedule II Controlled Substance Invoices	2 years
Schedule III – V Controlled Substance Invoices	2 years
Non-Controlled Substance Invoices (including OTC's and Supplies)	6 months
PSE Invoices and related purchasing documents (GA)	3 years
PSE Logbooks (all states)	2 years
DEA Form 222s	2 years
DEA Form 106	2 years
CII Monthly Variance Report	2 years
CII Perpetual Inventory Book	2 years
Annual CII Inventories	2 years
SHARPS Waste-Manifest Tracking Document (Generator Copy)	3 years
SHARPS Destruction Document	3 years
Temperature Log for Vaccines	3 years
Medication Therapy Management (MTM) Documentation	10 years
Copy of Pharmacist time sheets	2 years
Publix Diabetes Health Newsletter Registration Form	1 year
Medical Record Release Authorization (old)	6 years
Authorization for Release of Protected Health Information	6 years

continued on next page

Document Retention and Disposal, Continued

Time requirements, cont'd

Document	Retention Time
Request For Restrictions	6 years
Request For Confidential Communications	6 years
Request To Access Protected Health Information	6 years
Request To Amend A Record	6 years
Request For Accounting Of Disclosures	6 years
Privacy Complaint Form	6 years
Pharmacy Technician Training Records (Module Completion Records, Program Completion Record and Completion Certificate) (FL Only)	3 years
Weekly Memos & Monthly Focus Memos	3 months
Subpoena requests	1 month

QRE document retention

The completed *QRE Initial Report and Analysis* forms should be maintained until the next PPCQIP Quarterly Meeting behind the appropriate tab in your Information Binder.

Retain and dispose of QRE documents after the PPCQIP Quarterly Meeting according to the following chart:

State	After your PPCQIP Quarterly Meeting…

Florida	• shred the *QRE Initial Report and Analysis* forms
	• make a copy of the following completed forms for your Pharmacy Supervisor and keep the original in your Pharmacy's Accordion File for 2-years making it available for inspectors if requested:
	  • *PPCQIP Quarterly Meeting Agenda*
	  • *Summarization of QREs*
	• Each Pharmacy Supervisor must shred all forms as soon as you complete your review.)

All other states	• shred the *QRE Initial Report and Analysis* forms
	• send the following completed forms to your Pharmacy Supervisor (do not retain copies in your pharmacy)
	  • *PPCQIP Quarterly Meeting Agenda*
	  • *Summarization of QREs*

Note: Each Pharmacy Supervisor must shred all forms as soon as you complete your review.

Shredding expired retained documents

Shred all retained Pharmacy documents once their retention deadline expires. All Pharmacies must go through this document disposal process at least twice a year.

Stipulations (Florida Only)

Definition

Stipulations are specified actions based on an administrative complaint made by the Agency of Health Care Administration to the Florida Board of Pharmacy and the respondent (Publix Pharmacy or Pharmacist).

Introduction

This section explains the Publix policy regarding stipulations made to the Board of Pharmacy.

Policy

Whenever a Publix Pharmacist receives a stipulation, he or she must immediately contact his or her Pharmacy Supervisor. The Pharmacy Supervisor will then notify the Manager of Pharmacy Operations and the Vice President of Pharmacy.

If the Vice President of Pharmacy, the Manager of Pharmacy Operations, and the Pharmacy Supervisor determine the alleged activities contained in the Administrative Complaint occurred in the course and scope of the Pharmacist's employment, Publix will

- pay the administrative fine and the administrative costs imposed by the Board of Pharmacy against the license of the Pharmacist and
- retain, if necessary, as determined by the Vice President of Pharmacy and the Publix General Counsel, an attorney to represent the Pharmacist and/or Publix Super Markets, Inc.

The *Positive Formulary* and the *Negative Formulary*

Positive Formulary **(Florida only)**

The *Positive Formulary* lists all the preferred generic drugs that should be used in the Pharmacy. Publix Pharmacies receive generic drugs from the Publix Pharmacy Warehouse and from wholesalers. Wholesalers should only send us generic drugs listed on the *Positive Formulary*. You're required to make the *Positive Formulary* available to the public, Board of Pharmacy, or any physician who requests it.

This list is located in on Publix Connection on the pharmacy portal page – *Procurement* > *Positive Formulary (FL).* It is useful for locating the

- brand name equivalent
- pack size and the NDC number
- A.W.P. rating (average wholesale price) and
- drug reorder number.

Negative Formulary **(Florida only)**

The *Negative Formulary* lists generic drugs that were not found to be the equivalent to the name brands by the Board of Pharmacy of a particular state.

Note: Florida is the only state Publix operates in that has a *Negative Formulary*. See the Florida Pharmacy's Laws (Rules) for a current list of negative formulary drugs.

Identifying Invalid Controlled Substance Prescriptions - Overview

Introduction

It's important to comply with Drug Enforcement Agency (DEA) and state regulations regarding the dispensing of controlled substances not only for the safety of your patients, but also to minimize consequences for Publix and Publix associates. To that end, Publix Pharmacy is committed to minimizing the dispensing of controlled substances based on fraudulent representations which is the focus of this policy.

Your responsibility

Fraudulent representations are situations where a prescription is deceptively presented to your pharmacy as a valid prescription when in reality it is not valid. You are responsible for minimizing the dispensing of controlled substances based on fraudulent representations. This responsibility includes

- identifying and guarding against invalid practitioner-patient relationships
- guarding against filling fraudulent prescriptions for controlled substances
- identifying prescriptions that are communicated or transmitted illegally to avoid filling them
- identifying the characteristics of a forged or altered prescription to avoid filling them

Identifying Invalid Controlled Substance Prescriptions – Prescription Requirements

Introduction

To identify suspicious or fraudulent prescriptions, it's important to understand requirements associated with controlled substance prescriptions.

Requirements for controlled substance prescriptions

Pharmacy associates should know the requirements for a controlled substance prescription. The requirements for your state are detailed in the Reception Basics document on the pharmacy portal page – *Training & Development > Focus Topics > Reception Basics.*

Schedule II

Schedule II prescriptions may only be dispensed if the original hard copy of the written, signed prescription is presented to the pharmacy.

See the DEA's website for the Code of Federal Regulations, section 1306.11, for exceptions. There are situations where a fax or oral prescriptions may be appropriate, but there are specific DEA requirements for handling these situations.

Also, refer to your state regulations.

Other Schedules

Schedule III, IV and V prescriptions may be dispensed with receipt of a written prescription, fax received directly from the prescriber's office, or orally.

See the DEA's website for the Code of Federal Regulations, section 1306.21, for exceptions.

Also, refer to your state regulations.

Electronic transmission

Controlled substances (CIIs – CVs) can not currently be electronically transmitted to Publix from prescribers at this time. Although DEA regulations have been passed to allow this; other requirements regarding certification of prescriber and pharmacy systems are still in progress.

Identifying Invalid Controlled Substance Prescriptions – Minimizing Risk of Dispensing

Introduction

To minimize the dispensing of controlled substances based on fraudulent representations, it's important for a pharmacy associate to first identify suspicious or fraudulent activity or prescriptions. If a pharmacy associate discovers a suspicious or fraudulent controlled substance prescription the pharmacist on duty should be notified and the prescription should not be filled until its validity can be verified.

Examples of suspicious activity or prescriptions

Always use professional judgment when assessing situations; however, consider this list of potential suspicious activity that may indicate an invalid controlled substance prescription is being presented to you in the pharmacy.

- The prescriber's practice is not near where the patient resides.
- The prescriber writes significantly more prescriptions (or in larger quantities) compared to other practitioners in your area.
- The patient appears impaired or his/her behavior is suspicious.
- The patient appears to be returning too frequently. (A prescription which should have lasted for a month in legitimate use, is being refilled on a biweekly, weekly or even a daily basis.)
- The patient requests early refills or states that the previous fill was lost or stolen.
- The patient changes prescribers frequently ("doctor shopping").
- The patient has multiple controlled substance prescriptions.
- A new patient presents a prescription for a large quantity of a controlled substance.
- The patient only pays cash for controlled substance prescriptions.
- The prescriber writes prescriptions for central nervous system (CNS) drugs, such as depressants and stimulants, at the same time. Some drug abusers often request prescriptions for "uppers and downers" at the same time.
- The patient presents prescriptions written in the names of other people.
- A number of patients appear simultaneously, or within a short time, all bearing similar prescriptions from the same physician.
- Numerous people who are not regular patrons or residents of your community, suddenly show up with prescriptions from the same physician.

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Identifying Invalid Controlled Substance Prescriptions – Minimizing Risk of Dispensing, Continued

Types of fraudulent activity or prescriptions

Always use professional judgment when assessing situations; however, consider this list of potential ways that a fraudulent controlled substance prescription may be presented to you in the pharmacy.

- For those prescriptions required to be written on tamper resistant paper, a legitimate tamper resistant prescription pad could be stolen from a physician's office and used to write prescriptions for fictitious patients.
- A prescription could be altered by a patient in an effort to obtain additional amounts of legitimately prescribed drugs.
- A prescription pad from a legitimate doctor could be printed with a different call-back number where a drug abuser or accomplice verifies the prescription.
- A prescription could be called in by a drug abuser or accomplice providing their own telephone number as a call back confirmation.
- A prescription could be created from a home computer or a copy of a prescriber's legitimate prescription.

Indentifying & guarding against invalid practitioner-patient relationships

Pharmacy associates should know how to identify an invalid practitioner-patient relationship. Some ways to do this are

- checking the prescriber's address to determine if it is the same general area as the patient's address
- checking the state's Prescription Drug Monitoring Program (PDMP) database to determine information such as frequency of fills, use of particular prescribers, dispensing of excessive quantities, filling at multiple pharmacies, etc.

  Note: If the pharmacy receives notice from the Florida PDMP program that within any 90-day period the patient has received prescriptions for controlled substances from more than one prescriber and had these prescriptions filled by five or more pharmacies, this indicates drug abuse as set forth in Rule 64K-1.007, FAC
- looking up the prescriber's contact information via another source (use the pharmacy system, Prescriber ID lookup and/or DEA lookup tools as necessary) and contacting the prescriber directly to validate the prescription

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Identifying Invalid Controlled Substance Prescriptions – Minimizing Risk of Dispensing, Continued

Guarding against filling fraudulent prescriptions

Pharmacy associates should take the following actions in reviewing a controlled substance prescription.

- Carefully examine controlled substance prescriptions against the DEA and state requirements (see pg. 8-33).
- Evaluate that any faxed, transmitted, or orally prescribed prescriptions meet DEA and state requirements (see pg.8-33).
- Verify that controlled substance prescriptions are written on the required tamper resistant form when required by law.

  Note: For Florida, use the Approved Vendor Verification link on the pharmacy portal to assist you.
- Check the prescription to determine whether any information on the prescription has been altered.
- Check the prescriber's signature to make sure that it appears legitimate.
- For oral prescriptions, verify that the call came from the prescriber's office (e.g., if unsure or suspicious, call the office back using the phone number from our records).
- For oral prescriptions, verify that the caller is on the prescriber's staff (e.g., if unsure or suspicious, call the office back using the phone number from our records).
- For faxed prescriptions, make sure that the fax transmission came directly from the prescriber's office.
- Call the prescriber using the number on file if there are any questions.
- At pick-up, check the person's identification and verify that it is the person named on the prescription.

  Note: Some states have more strict guidelines to capture identification numbers in the pharmacy system. Follow the requirements in your state.

Identifying prescriptions communicated or transmitted illegally

Pharmacy associates should carefully examine written, faxed or transmitted controlled substance prescriptions to try to ascertain if they are legitimate. Refer to the guidance in the above section, **Guarding against filling fraudulent prescriptions,** on pg. 8-36.

Note: All Florida controlled substance prescriptions are required to be on tamper resistant prescription paper. Also, CMS requires that all Medicaid prescriptions be on tamper resistant prescription paper.

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Identifying Invalid Controlled Substance Prescriptions – Minimizing Risk of Dispensing, Continued

Identifying characteristics of a forged or altered prescriptions

Pharmacy associates should be able to identify characteristics of a forged or altered prescription. Some ways to do this are to determine if the

- prescription looks "too good" - the prescriber's handwriting is too legible
- prescription does not comply with the acceptable standard abbreviations or appear to be textbook presentations
- prescription appears to be photocopied
- directions are written in full with no abbreviations
- person other than the patient attempts to fill the prescription
- prescription is written in different color inks or written in different handwriting, or
- prescription is often paid for in cash.

Identifying Invalid Controlled Substance Prescriptions – Handling and Reporting

Introduction

It's important to properly handle a suspected invalid controlled substance prescription to protect Publix and comply with the law.

Handling prescriptions that don't meet the requirements

A pharmacy associate shall immediately notify the pharmacist on duty of any discovery of an attempt to obtain or instance where controlled substance was obtained through fraudulent methods or representations. If a prescription appears to be a invalid or fraudulent, the pharmacy associate shall not fill the prescription until the pharmacist consults with the prescriber and verifies that the prescription is valid or otherwise determines the legitimacy of the prescription.

Reporting of fraudulent prescriptions

Upon learning of any instance in which a person obtained or attempted to obtain from the pharmacy a controlled substance through fraudulent methods representations, ensure the pharmacist on duty is notified. Then, the pharmacist on duty must notify the Pharmacy Supervisor.

Identifying Invalid Controlled Substance Prescriptions – E-FORCSE (FL) Requirements

About E-FORCSE

Electronic-Florida Online Reporting of Controlled Substances Evaluation (E-FORCSE) is Florida's controlled substance monitoring program. This is an online database established to record all controlled substance prescriptions filled in the state. This database gives pharmacists the ability to look at a patient's purchase history of controlled substances. Pharmacists can then use the information to make judgment decisions about whether or not to fill a controlled substance for a patient.

Publix expectations for E-FORCSE use

All Publix pharmacists are required to create a personal account and use the website database to identify whether or not dispensing certain controlled substance prescriptions is appropriate. Use this database any time you feel in your professional judgment as a pharmacist that it is necessary to check the patient's history.

Refer to various examples of suspicious or fraudulent activity that may drive you to use this database by reviewing the information starting on pg. 8-34.

Handling E-FORCSE results

If the E-FORCSE database shows that the customer is filling at multiple pharmacies, purchasing excessive quantities of controlled substances, filling prescriptions early or using multiple doctors, you should inform the customer that you will not be able to fill the controlled substance prescription.

- If this is an *existing customer*, document your decision in a *Patient Note* (example: Checked E-FORCSE - Patient filling CS Rxs at multiple pharmacies).
- If this is not an existing customer who is not in our system, no further action is needed.

If you choose to fill the Rx after reviewing the patient's history in the database, document your decision in an *Rx Note (i.e.,* "Checked E-FORCSE") and fill the prescription.

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Identifying Invalid Controlled Substance Prescriptions – E-FORCSE (FL) Requirements, Continued

Setting up an E-FORCSE account

To setup an account, access the E-FORCSE website from Pharmacy Online at: *Pharmacy Boards and Government Agencies > Florida Controlled Substance Monitoring Program (E-FORCSE)*. Then click the *Practitioner/Pharmacist* link and follow the instructions.

Note: You will have to use your personal home email address to receive your account login information.

Accessing patient information on E-FORCSE

Follow these steps to look up customer information from the E-FORSCE site.

1. Click the *Practitioner & Pharmacist Query Site* link.
2. Login and click *Practitioner/Pharmacist Query*, then click the button to accept the site's conditions of use.
3. Enter the patient's last name, first name and DOB and click *Submit* to run the searc.
4. From the presented list of patients, select the correct patient and click *Request.*

Loss Prevention Investigations

Introduction

As part of an investigation, a Publix Loss Prevention Specialist may request a minimum necessary amount of an associate's prescription information from the Pharmacy. Providing an associate's prescription information is an allowable disclosure of PHI under the Privacy Rules, as it is considered part of health care operations (conducting or arranging for medical review, legal, and auditing services, including fraud and abuse detection and compliance programs). The Pharmacy is not required to account for PHI disclosures of this type.

Providing an associate's prescription information to a Loss Prevention Specialist

Follow these steps to provide an associate's prescription information to a Loss Prevention Specialist.

Note: Be sure to only provide the minimum necessary amount of information needed to conduct the investigation. For example, only provide the prescription date and prescription cost if that's enough information to conduct the investigation. Do not provide the prescription name unless it is needed for the investigation and the request has been approved.

<table>
<tr><th>Step</th><th>Who</th><th>Action</th></tr>
<tr><td>1</td><td rowspan="2">Loss Prevention Specialist</td><td>Request an associate's prescription information needed to conduct an investigation. Is the prescription name needed?
<table>
<tr><th>If...</th><th>Then...</th></tr>
<tr><td>yes</td><td>contact the Pharmacy Supervisor and Privacy Officer for approval. Go to step 2.</td></tr>
<tr><td>no</td><td>go to step 3.</td></tr>
</table></td></tr>
<tr><td>2</td><td>Did the Pharmacy Supervisor and Privacy Officer approve the request for the prescription name?
<table>
<tr><th>If...</th><th>Then...</th></tr>
<tr><td>yes</td><td>the Pharmacy Supervisor will notify the Pharmacist that he or she can release the prescription name. Go to step 3.</td></tr>
<tr><td>no</td><td>the Pharmacist cannot supply the prescription name. The investigation will need to be conducted without the use of the prescription name.</td></tr>
</table></td></tr>
<tr><td>3</td><td>Pharmacist</td><td>Receive request and provide the Loss Prevention Specialist with the requested prescription information.</td></tr>
<tr><td>4</td><td>Loss Prevention Specialist</td><td>Conduct the investigation and secure the prescription information obtained during the investigation.
Note: Always store Confidential Incident Reports and all supporting documentation in a locked file cabinet.</td></tr>
</table>

Losses and Theft of Controlled Substances

Introduction

We're legally obligated to report thefts and/or significant losses of controlled substances to the DEA.

Immediate reporting of suspected thefts and/or significant losses to the DEA

Contact your Pharmacy Supervisor to help you determine whether a loss is "significant."

Thefts and/or significant losses must be reported to the DEA within one business day of discovery. **Contact your Pharmacy Supervisor** to prepare the report. It should be a short statement that is faxed to the local DEA office.

Reporting thefts and/or significant losses to the DEA using Form 106

Once circumstances surrounding the theft and/or significant loss are clear the DEA should be notified using *DEA Form 106*. **Contact your Pharmacy Supervisor** to help you complete the *DEA Form 106*.

Note: The *DEA Form 106* can be found on the DEA website. Once on the pharmacy page of Publix Connection, go to *Pharmacy Boards and Government Agencies > DEA – Diversion Control Program*. Then on the DEA's website find the DEA Form 106 in the Quick Links section. Once you begin the form it will ask for:

- your pharmacy's DEA number, and
- a last name which is "Publix Super Markets"

Reporting thefts and/or significant losses to Loss Prevention

Thefts and/or significant losses of controlled substances should also be reported to Publix's Loss Prevention Department with the help of your Pharmacy Supervisor. This chart provides contact information for Loss Prevention.

Division	Contact	Phone Number
Atlanta	Mike Zilleox	Office – (770) 952-6601, ext. 3752 Cell – (404) 456-1887
Jacksonville	Nolan Bomar	Office – (904) 781-8600, ext. 2478 Cell – (904) 370-4745
Lakeland	Joe Williams	Office – (863) 688-1188, ext. 24510 Cell – (863) 670-5893
Miami	Keith Hunter	Office – (305) 652-2411 ext. 2827 Cell – (954) 553-0286

Handling Suspicious Substances or Packages

Summary

Knowing what to do when you come across a suspicious substance or package is important. Publix provides information on this process in the Retail Managers Reference Library (MRL), kept by your Store Manager.

Who to Contact

If you come across any suspicious substances or packages please contact your Store Manager immediately.

Price Override Policy

Introduction

It may become necessary to override the price (match a price) on a prescription due to pricing errors in the pharmacy system or lack of competitiveness with the local market on a particular prescription item. Please review this policy before completing an override.

Policy

The following guidelines must be followed each time a price is overridden in the pharmacy system.

- Low cost generic programs cannot be matched (e.g. $4 generic program).
- Prices resulting from membership in special programs at competitors cannot be matched.
- The price must be verified on each fill of the prescription.
- A Transaction Note (TX Note) must be entered on every prescription fill (including refills) indicating the specific competitor and price that was matched.
- Only local competitors may be matched. A local competitor is defined as a local retail pharmacy within convenient driving distance.
- Internet pricing cannot be matched.
- The pricing disparity should be reported to Pharmacy Operations.

Purchase Policy

Introduction

All Publix associates must pay the full retail price that Publix has established for their own purchases.

Policy

All products, including those ordered through our Pharmacy wholesaler and OTC items, must be purchased by associates for the full retail price and must not be discounted. This includes purchases for yourself or on behalf of others. You're not permitted to discount merchandise or accept discounted merchandise unless the merchandise is discounted by Publix.

The entire Purchase Policy is on page 3-15 of Your Associate Handbook. You can find the handbook on Publix Connection under *Resources* → *Benefits* → *Your Associate Handbook*.

Enforcement

Failure to pay the full retail price for any item will result in termination of employment.